


**Laboratory of
Immunobiochemistry**

Operational issues




B staffing

Full time

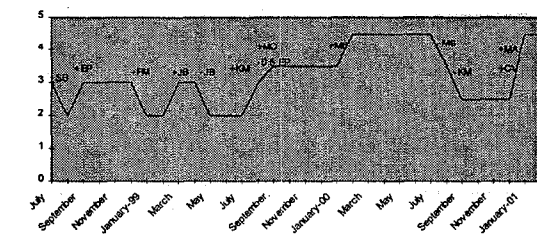

- Jay E. Slater, MD - Lab Chief (2.5)
- Lyudmila Soldatova, PhD - Visiting Scientist (3.5)
- Melissa Patterson - Biologist (1.5)
- Mona Febus - Microbiologist (1)
- William J. Finlay, PhD - IRTA Fellow
- Marc Alston - Biologist
- Cherry Valerio - Biologist
- Albert Gam - Biologist
- Ronald Rabin, MD - Senior Staff Fellow

Part time


- Elizabeth Cardinale - Biologist
- Gerald Poley, MD - Guest Worker
- Li Shan Hsieh, PhD - CDER



B Biologist staffing 1998-2001

Reference replacement activities



"Routine" regulatory activities


Reference development

Reference distribution

- 1999: 1983 vials in 104 shipments sent to manufacturers
- 2000: 2384 vials in 146 shipments sent to manufacturers


Reference maintenance

- semiannual checks
- replacement



Reference replacement procedure

- Identify references to be replaced
- Select candidates from recent submissions
- Initial testing in LIB/CBER
- Select provisional reference replacement
- Send provisional replacement to manufacturers
- Review results; confirm selection OR go back to step 2



References replaced in 2000

Reference	Initial evaluation	Manufacturers participating	Shipped
E6 - sweet vernal	4/00	3	12/00
S6 - Opl	8/00	10/9	11/00
S6 - anti Amb a 1	8/00	6	8/00
E8 - Df mite	10/00	4	12/00

References replaced since 10/99

Reference	RP (of new reference using old)	RP (of old reference using new)
E6-red top	1.01 (0.88-1.14)	0.99 (0.87-1.12)
E6-orchard grass	0.88 (0.75-0.99)	0.97 (0.86-1.09)
E6-meadow fescue	1.01 (0.90-1.13)	0.90 (0.80-1.02)
E6-sweet vernal	0.71 (0.46-1.10)	0.63 (0.54-1.29)
E8-Df mite	1.04 (0.73-1.49)	0.95 (0.66-1.36)

References to be replaced in 2001:

On the basis of volume remaining:

- Anti-Fel d 1 serum
- Cat hair

■ On the basis of nominal expiry:

- Bermuda grass
- rye grass
- Kentucky blue grass
- timothy grass
- ragweed
- cat pelt

Reference replacement program - switch to lyophilized extracts

1999-00 : LIB will lyophilize a portion of all new reference extracts

■ 2000-03 : LIB will assess stability and reliability of lyophilized products

■ Results and samples will be distributed to APMA membership prior to action

Guidance for Reviewers

Potency Limits for Standardized Dust Mite and Grass Allergen Vaccines: A Revised Protocol

Additional copies are available from:
Office of Communications, Training and Manufacturer Assistance (OTMA)
1401 Rockville Pike, Rockville, MD 20852-1480
(Tel) 301-457-1100
or 301-457-1300
(Internet) <http://www.fda.gov/oc/otma.htm>

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research
November 2000

Guidance for Industry

Testing Limits in Stability Protocols for Standardized Grass Pollen Extracts

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